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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,370	07/25/2003	Jason M. Johnson	RS0202Y	3302

7590 11/29/2004
R. Douglas Bradley
Merck & Co., Inc.
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EXAMINER

HOWARD, ZACHARY C

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 11/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/627,370	Applicant(s) JOHNSON ET AL.	
	Examiner Zachary C Howard	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Advisory Information

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

The instant specification will need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. For rules interpretation Applicant may call (703) 308-1123. See M.P.E.P. 2422.04.

Each sequence shown in the Figures must be identified by reference to a sequence identifier number (SEQ ID number) in either the Figure, or in the Brief Description of the Figures. Figures 2A and 3A each contain two sequences and Figures 2B and 3B each contain one sequence, none of which are referred to by SEQ ID number in either the Figure in question, or in the Brief Description of the Figures.

Applicant's cooperation is requested in correcting any other sequences, or references to sequences, in the specification or claims that do not include a sequence identifier, and that applicant becomes aware of.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

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- I. Claims 1-3, 6-12, drawn to a nucleic acid, vector, host cell, and method of recombinantly producing a protein, classified in class 536, subclass 23.5, class 435, subclasses 320.1, 252.3, and 69.1, for example.
- II. Claims 4-5, drawn to a protein, classified in class 530, subclass 350.
- III. Claims 13-22, drawn to a method of screening for compounds able to bind selectively to CACNA1Bsv1, classified in class 435, subclass 7.2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged.

The polynucleotide of Group I and the polypeptide of Group II are patentably distinct for the following reasons: polypeptides (composed of amino acids) and polynucleotides (composed of purines and pyrimidines) are structurally distinct molecules; any relationship between them depends upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Furthermore, the search of the inventions of Group I and II together would impose a serious search burden. The two inventions have a separate status in the art as shown by their different classifications. In cases such as this where descriptive sequence information is provided, the protein and nucleic acid sequences are searched in databases that are not coextensive. In addition, the technical literature search is not coextensive. A protein may be described in the literature prior to the concomitant isolation and expression of the nucleic acid sequence. Similarly, there may be "classical" genetics papers that describe the gene but not the polypeptide. Furthermore, a search of the nucleic acid sequences of Group I would

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require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of Group II.

Inventions I and III are related in that the nucleic acid of Invention I encodes the protein used in the process of Invention III. The nucleic acid and protein are independent and distinct for the reasons set forth. The nucleic acid of Invention I and the process of using the protein of Invention III are also independent and distinct because the nucleic acid of Invention I can be used in a method of detecting the presence of a gene in a sample by hybridization, which is a materially different process that does not require the protein.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein can be used in a method of screening for compounds that can bind selectively to the protein, but the protein could also be used in a method of generating antibodies, which is a materially different process.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements and/or divergent subject matter, restriction for examination purposes as indicated is proper.

A telephone call was made to R. Douglas Bradley on 11/19/2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eileen B. O'Hara

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EILEEN B. O'HARA
PATENT EXAMINER